IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No.: 07-805 (JJF) JURY TRIAL DEMANDED

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS
OF DEFENDANT MYLAN PHARMACEUTICALS INC.

Defendant Mylan Pharmaceuticals Inc. ("Mylan") hereby answers the Complaint of Plaintiffs AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharma"), AstraZeneca UK Limited ("AstraZeneca UK"), IPR Pharmaceuticals, Inc. ("IPR"), and Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") (collectively "Plaintiffs") as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. §§ 271(e) and (a). This action relates to an Abbreviated New Drug Application ("ANDA") filed by Mylan Pharmaceuticals Inc. ("the Mylan ANDA") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' highly successful Crestor® pharmaceutical products that are sold in the United States.

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that this action purports to be an action for alleged patent infringement; and that Mylan has submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") for Rosuvastatin

Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg. Mylan denies the remaining allegations of this Paragraph.

Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore denies the same.

3. Plaintiff AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore denies the same.

4. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore denies the same.

5. Plaintiff Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore denies the same.

6. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation operating and existing under the laws of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504 USA.

ANSWER: Admitted.

Background

7. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Tablets, in Crestor® 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

ANSWER: Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that the electronic version of FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book), identifies "IPR" as the applicant for approved New Drug Application ("NDA") No. 21-366 for Crestor® (rosuvastatin calcium) Tablets, 5 mg, 10 mg, 20 mg, and 40 mg. Mylan denies the remaining allegations of this Paragraph.

8. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Crestor® is one of the most effective lipid-lowering statins available. Over 11 million patients have been prescribed Crestor®, and over 110 million prescriptions have been written worldwide for Crestor®.

ANSWER: Mylan admits that the FDA-approved product labeling for Crestor® (rosuvastatin calcium) states that Crestor® is a HMG-CoA reductase inhibitor indicated for, among other things, as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore denies the same.

9. Plaintiffs, among other things, manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new indications for Crestor® Tablets. Plaintiffs financially benefit from sales of Crestor® Tablets in the United States.

ANSWER: Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore denies the same.

10. On information ond belief, Mylan filed with the FDA, in Rockville, Maryland, ANDA No. 79-161 under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are generic versions of Plaintiffs' Crestor® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, respectively.

ANSWER: Mylan admits that it has submitted an ANDA to FDA seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg. Mylan denies the remaining allegations of this Paragraph.

11. By letter dated November 13, 2007, Mylan notified Plaintiffs that it had filed an ANDA seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths (hereinafter referred to as "the Mylan Rosuvastatin Calcium Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(i), (ii), (iii), and (iv).

ANSWER: Mylan admits that, in a letter dated November 13, 2007, entitled "Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. RE 37,314 E and 6,316,460 B1 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act," Mylan duly notified AstraZeneca Pharms, IPR and Shionogi that Mylan had filed an ANDA with a so-called "paragraph IV certification" seeking approval to engage in the commercial manufacture, use or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, prior to the expiration of the U.S. Patent No. RE 37,314 E ("the '314 patent"). Mylan denies the remaining allegations of this Paragraph.

12. On information and belief, Mylan is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Mylan markets, distributes, and sells generic pharmaceutical products throughout the United States, including the State of Delaware.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that it develops and manufactures quality generic medicines. Further answering, to conserve the resources of the parties and Court, Mylan does not contest personal jurisdiction or venue for purposes of this action only. Mylan denies the remaining allegations of this Paragraph.

Jurisdiction and Venue

13. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that this Court has subject matter jurisdiction for the claims asserted against Mylan under 35 U.S.C. § 271(e)(2)(A). Mylan denies the remaining allegations of this paragraph.

14. On information and belief, Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Personal jurisdiction over Mylan is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Mylan places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, to conserve the resources of the parties and Court, Mylan does not contest personal jurisdiction for purposes of this action only. Mylan denies the remaining allegations of this Paragraph.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 (c) and 1400(b).

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, to conserve the resources of the parties and Court, Mylan does not contest venue for purposes of this action only. Mylan denies the remaining allegations of this Paragraph.

Count I

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

16. Plaintiffs incorporate by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

ANSWER: Mylan repeats its answers to Paragraphs 1-15 as though fully set forth herein.

17. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on

August 7, 2001. Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that, according to the records of the U.S. Patent and Trademark Office ("PTO"), on or about August 7, 2001, the PTO reissued the '314 patent, entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe; that the cover page of the '314 patent identifies "Shionogi Seiyaku Kabushiki Kaisha" as the assignee; and that what purports to be a copy of the '314 patent is attached to the Complaint as Exhibit A. Mylan expressly denies that the '314 patent was "duly and legally reissued." Mylan denies the remaining allegations of this Paragraph.

18. On information and belief, Mylan filed ANDA No. 79-161 in order to obtain approval to market the Mylan Rosuvastatin Calcium Tablets in the United States before the expiration of the '314 patent. On information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '314 patent are invalid and not infringed and that the '314 patent is unenforceable.

ANSWER: Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Mylan admits that it has submitted an ANDA to FDA seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg; and that Mylan's ANDA contains a so-called "paragraph IV certification" seeking to obtain approval to engage in the commercial manufacture, use or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, prior to the expiration of the '314 patent. Mylan denies the remaining allegations of this Paragraph.

19. Under 35 U.S.C. § 271(e)(2)(A), the submission by Mylan to the FDA of ANDA No. 79-161 to obtain approval for the commercial manufacture, use, or sale of the Mylan Rosuvastatin Calcium Tablets before the expiration date of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

20. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count II

Declaratory Judgment of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(a)

21. Plaintiffs incorporate by reference paragraphs 1-20 of this Complaint as if fully set forth herein.

ANSWER: Mylan repeats its answers to Paragraphs 1-20 as though fully set forth herein.

22. Upon information and belief, Mylan has made substantial preparations to sell Mylan Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor® products.

ANSWER: Mylan admits that it has submitted an ANDA to FDA seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg; and that Mylan's ANDA contains a so-called "paragraph IV certification" seeking to obtain approval to engage in the commercial manufacture, use or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, prior to the expiration of the '314 patent. Mylan denies the remaining allegations of this Paragraph.

23. Upon information and belief, Mylan intends to commence sale of Mylan Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.

ANSWER: Mylan admits that it has submitted an ANDA to FDA seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg; and that Mylan's ANDA contains a so-called "paragraph IV certification" seeking to obtain approval to engage in the commercial manufacture, use or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, prior to the expiration of the '314 patent. Mylan denies the remaining allegations of this Paragraph.

24. The manufacture, importation, sale, and offer for sale of Mylan Rosuvastatin Calcium Tablets, once approved by the FDA, will directly infringe, induce and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a).

ANSWER: Denied.

25. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

26. An actual controversy exists relating to Mylan's threatened infringement of the '314 patent.

ANSWER: Denied.

* * *

Mylan denies all remaining allegations not specifically admitted herein. Mylan further denies that Plaintiffs are entitled to the relief requested, or to any relief whatsoever. Mylan respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Mylan; (c) award Mylan the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Mylan such further relief as the Court deems just and appropriate.

DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendant Mylan Pharmaceuticals Inc. avers and asserts the following defenses to the Complaint:

First Defense

The claims of U.S. Patent No. RE 37,314 E ("the '314 patent") are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Second Defense

The manufacture, sale, use, offer for sale, or importation of Mylan Pharmaceuticals Inc.'s proposed rosuvastatin product, that is the subject of its ANDA, would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '314 patent.

Third Defense

The Complaint fails to state a claim upon which relief can be granted.

Fourth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), for its Counterclaims against AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharma"), AstraZeneca UK Limited ("AstraZeneca UK"), IPR Pharmaceuticals, Inc. ("IPR"), and Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") (collectively "Plaintiffs"), alleges as follows:

The Parties

1. Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

2. AstraZeneca Pharma purports to be a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

3. AstraZeneca UK purports to be a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England.

4. IPR purports to be a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

5. Shionogi purports to be a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

Jurisdiction and Venue

6. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28, U.S.C. §§ 2201 and 2202.

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Mylan in this District, and/or because Plaintiffs conduct substantial business in this District.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

Patent-in-Suit

9. On or about August 7, 2001, the U.S. Patent and Trademark Office ("PTO") reissued U.S. Reissued Patent No. RE 37,314 E ("the '314 patent"), entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

10. Plaintiffs purport and claim to own, and to have the right to enforce, the '314 patent.

11. On or about December 11, 2007, Plaintiffs sued Mylan in this District alleging infringement of the '314 patent under 35 U.S.C. § 271(e)(2)(A).

Count I
(Declaratory Judgment of Invalidity of the '314 Patent)

12. Mylan re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

13. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs regarding the invalidity of the '314 patent.

14. The claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

15. Mylan is entitled to a judicial declaration that the claims of the '314 patent are invalid.

Count II
(Declaratory Judgment of Non-Infringement of the '314 Patent)

16. Mylan re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

17. There exists an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs regarding non-infringement of the '314 patent.

18. The manufacture, use, sale, offer for sale, or importation of the rosuvastatin tablets that are the subject of Mylan's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid claim and/or enforceable claim of the '314 patent.

19. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the rosuvastatin tablets that are the subject of Mylan's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent.

Prayer for Relief

WHEREFORE, Mylan respectfully prays for judgment in its favor and against Platintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the rosuvastatin tablets that are the subject of Mylan's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent;

(b) Declaring that the claims of the '314 patent are invalid;

(c) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Mylan;

(d) Declaring this case exceptional and awarding Mylan its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding Mylan such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Mylan hereby demands a jury trial on all issues so triable.

Dated: January 31, 2008

By: _____

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